UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 4 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN TESTIMONY OF JULIE DROLET, M.D.

Dr. Drolet is a gynecologist with board certifications in Female Pelvic Medicine and Reconstructive Surgery and Obstetrics and Gynecology. *See generally* Ex. A, Julie Drolet, M.D., Curriculum Vitae ("Drolet CV"); Ex. B, Julie Drolet, MD, Expert Report on Prolift and Prolift +M (Feb. 1, 2017) ("Drolet Prolift Report"); Ex. C, Julie Drolet, M.D., Expert Report on TVT-O (Feb. 1, 2017) ("Drolet TVT-O Report"). She is without question a bona fide expert in the fields of pelvic medicine generally and in the surgical treatment of pelvic organ prolapse and stress urinary incontinence specifically.

Dr. Drolet issued two general reports in this Wave 4—one report concerns Prolift and Prolift+M; the other addresses TVT-O. Plaintiffs' Motion is not aimed at either of these two general reports. Instead, Plaintiffs incorporated by reference a challenge to Dr. Drolet's report in the Wave I case styled *Rose Gomez v. Ethicon, Inc.* Civ. A. No. 2:12-cv-344. *See* Notice of

Adoption [Dkt. 3649] (adopting by reference the Motion [Dkt. 2093] and Brief [Dkt. 2094] which challenged Dr. Drolet's report in *Gomez*).

Because Plaintiffs failed to challenge either of Dr. Drolet's general reports that are offered in this Wave 4, the inquiry should end there. Out of an abundance of caution, however, Ethicon will address the earlier challenge in *Gomez* to the extent that the *Gomez* report overlaps with these Wave 4 general reports.

At the outset, it should be noted that Plaintiffs have not challenged the overwhelming majority of Dr. Drolet's general opinions. Rather, Plaintiffs seek to limit Dr. Drolet's testimony on only eight points:

First, Plaintiffs contend that Dr. Drolet's discussion about pelvic organ prolapse, stress urinary incontinence, and the various treatment options constitute inadmissible narrative testimony. Dr. Drolet's discussion of pelvic organ prolapse, stress urinary incontinence, and the treatment options for same is not impermissible narrative testimony. Rather, the discussion of these medical conditions and treatment options informs the basis of Dr. Drolet's opinion regarding the propriety of Prolift, Prolift+M, and TVT-O as surgical options.

Second, Plaintiffs claim that Dr. Drolet's opinions regarding the risk profiles of TVT-O and Prolift+M are unsupported. Dr. Drolet fully supports her opinions regarding the risks and benefits of TVT-O and Prolift+M through her research and clinical experience with these products. Plaintiffs' desire to confront Dr. Drolet with documents that purportedly contradict her opinions goes to the weight, not admissibility, of her opinion testimony. The Court rejected this challenge in *Gomez* and should do so again here.

Third, Plaintiffs argue that Dr. Drolet is not competent to testify regarding the general state of medical knowledge regarding the risks associated with pelvic floor surgery. Dr. Drolet is

not attempting to testify regarding the state of mind or knowledge of any particular pelvic floor surgeon. Her testimony does touch upon what a reasonably prudent pelvic floor surgeon should know regarding pelvic medicine. This is not "state of mind" testimony, but is rather "standard of care" testimony, which is relevant to Ethicon's learned intermediary defense. As an expert in the field of pelvic medicine, Dr. Drolet is certainly competent to opine regarding the standard of care within her chosen specialty.

Fourth, Plaintiffs argue that Dr. Drolet is impermissibly attempting to opine regarding the intent of the medical device industry, Ethicon, and the FDA. Dr. Drolet makes no attempt to opine regarding the intent of the medical device industry, Ethicon, or the FDA as alleged by Plaintiffs. This argument is a red herring.

Fifth, Plaintiffs contend that Dr. Drolet is unqualified to opine regarding the significance of the FDA 510(k) clearance of TVT-O and Prolift+M. It remains Ethicon's position both that Dr. Drolet is both qualified to opine on such topics and that her opinions regarding same are relevant to the underlying dispute. This issue has been briefed previously and ruled upon by this Court on numerous occasions. Ethicon will not here reargue the issue, but rather will note its continuing position regarding same. Regardless, Dr. Drolet does not intend to opine on the significance of the FDA 510(k) clearance process. In her deposition, Plaintiffs asked Dr. Drolet questions regarding the clearance, and she answered those questions. Provided that Plaintiffs do not open the door, Dr. Drolet does not intend to offer this opinion. To the extent Plaintiffs open the door, Dr. Drolet should be entitled to respond.

Sixth, Plaintiffs claim that Dr. Drolet's opinions regarding the subject Instructions For Use ("IFUs") are unreliable. Contrary to Plaintiffs' arguments, Dr. Drolet's testimony is entirely consistent with the Court's prior rulings regarding practitioners opining on the IFU. Dr. Drolet

merely identifies the risks associated with non-mesh surgeries, identifies the risks associated with mesh surgeries, and discusses whether the relevant IFUs inform surgeons of the risks unique to mesh surgeries.

Seventh, Plaintiffs argue that Dr. Drolet seeks to offer improper legal conclusions. Dr. Drolet makes no improper legal conclusions. This too is a red herring.

Lastly, Plaintiffs aver that Dr. Drolet was unable to identify the documents that she relied upon in arriving at her opinions. This accusation is false. Plaintiffs did not depose Dr. Drolet in relation to her Wave 4 reports and have no basis for their contention. In relation to her *Gomez* report, Dr. Drolet fully identified the documents upon which she relied in arriving at her opinions. If there were documents in her possession which she did not review or documents available to her that she did not request, that goes to the weight, not admissibility, of her opinion testimony.

For these reasons, Plaintiffs' motion to limit Dr. Drolet's testimony should be denied.

ARGUMENT AND AUTHORITIES

I. Dr. Drolet's Opinion Testimony Regarding POP, SUI, and the Various Treatment Options Serve as the Bases for Her Other Opinions

Plaintiffs argue that Dr. Drolet's opinion testimony regarding POP, SUI, and the treatment options for same constitute impermissible narrative testimony. Pls.' Br. [Dkt. 2094] at 2-3. Contrary to Plaintiffs' assertion, Dr. Drolet's opinions on these points serve, in part, as the bases for her opinions regarding the safety, efficacy, and risk/benefit analysis regarding the use of Prolift, Prolift+M, and TVT-O. As this Court has held, "experts may form opinions by relying on facts that they have 'been made aware of,' as long as 'experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject.'" *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 646 (S.D.W. Va. June 4, 2013) (quoting Fed. R. Civ. P. 703).

Additionally, this Court has held that "to the extent that [factual narratives] may present the bases for their expert opinions in this case" such factual narratives are admissible. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589 at 646; *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, at *18–19 (S.D.W. Va. Feb. 7, 2015). Experts are not only entitled to explain the basis for their opinions, but the Federal Rules of Civil Procedure require that they do so. *See* Fed. R. Civ. P. 26(a)(2)(B) (expert's "report must contain . . . a complete statement of all opinions the witness will express and the basis and reasons for them . . . .").

Dr. Drolet's ultimate opinions in this case are that "Prolift and Prolift+M are reasonably safe for the intended use in treating pelvic organ prolapse when used by an experienced surgeon in an appropriately selected [] patient," Ex. B, Drolet Prolift Report at 37, and that "TVT-O is reasonably safe for its intended use," Ex. C, Drolet TVT-O Report at 31. To arrive at these opinions, Dr. Drolet must have an appreciation and understanding of the medical conditions for which the Prolift, Prolift+M, and TVT-O are intended to treat – POP and SUI. Dr. Drolet must know and understand the alternative surgical options. She must understand the risks and benefits of the other surgical options. She must understand the risks and benefits of the Prolift, Prolift+M, and TVT-O. Only after consideration of all of these things can she arrive at her opinions about the appropriateness and effectiveness of the Prolift, Prolift+M, and TVT-O surgeries.

Additionally, Dr. Drolet's discussions of POP, SUI, and the treatment options include specific citations to studies, articles, and authorities that pelvic surgeons, like Dr. Drolet, review and rely upon in their medical practice and treatment of their patients. *See, e.g.*, Ex. B, Drolet Prolift Report at 3-26; Ex. C, Drolet TVT-O Report at 3-22.

Plaintiffs' other objection regarding this testimony is that there may exist other studies or articles not cited by Dr. Drolet, which allegedly contradict the studies cited by Dr. Drolet. *See*

Pls.' Br. [Dkt. 2094] at 2. This argument does not go to the admissibility of Dr. Drolet's testimony; rather, this is an issue for cross-examination.

The Court rejected a similar argument in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521 (S.D. W. Va. May 19, 2016). The plaintiff in that case challenged defense expert Stephen Badylak, M.D.'s competence to testify about the safety and efficacy of polypropylene mesh devices on the basis that Dr. Badylak had admitted that he had not performed a "comprehensive review" of the scientific literature related to the defendant's devices." *Id.* at *40. The Court, however, noted that Dr. Badylak's report demonstrated that he "reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices," and that "[i]f there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Id.*; *see also id.* at *8 (S.D.W. Va. Apr. 28, 2016) (finding that "to the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their admissibility" and that "[t]he defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions").

Neither the law nor the rules of evidence or civil procedure require an expert witness to review each and every study, article, and paper published on a given topic or to explain in her report why she has elected not to rely upon a certain study, article, or paper. Plaintiffs are certainly entitled to question Dr. Drolet regarding the documents upon which she relied and her reasons for not relying on others. But this is a question for cross-examination, not for exclusion under *Daubert*.

Plaintiffs also make a passing objection to the fact that Dr. Drolet "does not offer an opinion regarding the complication or efficacy rates associated with the Prolift+M or TVT-O products." Pls.' Br. [Dkt. 2094] at 2. Plaintiffs argue that in the absence of such an opinion Dr. Drolet's other opinions are "unhelpful." *Id.* Plaintiffs cite nothing for the proposition that in the absence of an opinion regarding complication and efficacy rates, an expert's opinion is deemed unreliable.

More importantly though, Dr. Drolet throughout her report discusses her extensive review of medical literature, including Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials, including medical literature addressing the complication and efficacy rates observed, not to mention public statements by medical societies in the fields of urology. *See* Ex. B, Drolet Prolift Report at 14-27, 32-33; Ex. C, Drolet TVT-O Report at 3-22, 26-27. It is unclear from Plaintiffs' brief what more they contend Dr. Drolet allegedly should have done to render her opinion testimony "helpful."

Dr. Drolet's discussion of POP, SUI, and the various treatment options for these conditions form, in part, the bases of her opinions. These discussions do not constitute impermissible narrative testimony and are admissible.

II. Dr. Drolet's Opinions Regarding the Risk/Benefit Profile of TVT-O and Prolift+M Are Sufficiently Based Upon Her Knowledge of the Medical Literature and Her Clinical Experience

Plaintiffs generally argue that Dr. Drolet's opinions regarding the risk benefit profile of Prolift+M and TVT-O[1] are "unreliable" and "contradicted by the science she cites." Pls.' Br. [Dkt. 2094] at 3. In Wave I, the Court flatly rejected these arguments. *See* Mem. Op. & Order

[1] Because the *Gomez* case did not involve the Prolift and Plaintiffs incorporated by reference the arguments made in *Gomez*, their instant challenge does not include any arguments regarding Dr. Drolet's opinion about the risk benefit profile of Prolift.

[Dkt. 2694] at 6-7. Here, Plaintiffs offer no new or different arguments that would warrant deviating from the Court's prior ruling on this issue.

Plaintiffs contend that Dr. Drolet did not "disclose[] a reliable basis" for her conclusion regarding the risk benefit profile of Prolift+M and TVT-O. Pls.' Br. [Dkt. 2094] at 3. Plaintiffs' argument in this regard is nonsensical. For more than 20 pages of her reports, Dr. Drolet explains the medical conditions of POP and SUI, the risks and benefits of non-surgical treatments, the risks and benefits of non-mesh surgical treatments, and the risks and benefits of both mesh surgical treatments in general and Prolift+M and TVT-O surgical treatments specifically. *See, e.g.*, Ex. B, Drolet Prolift Report at 3-26; Ex. C, Drolet TVT-O Report at 3-22. Throughout these explanations, Dr. Drolet cites to the medical literature, the professional organization position statements, her education, her training, and her clinical practice, all of which support and form the reliable bases upon which her opinion is based.

As part of this argument, Plaintiffs contend that Dr. Drolet's opinion—that the benefits outweigh the risk—is somehow contrary to the 2011 American College of Obstetrician and Gynecology ("ACOG") 2011 committee opinion and that this alleged contradiction renders Dr. Drolet's opinion unreliable. This purported conflict between Dr. Drolet's opinion testimony and ACOG's committee opinion, again, is not a question of the reliability of Dr. Drolet's opinion. It is a question that goes to the weight of her opinion testimony to be addressed on cross-examination.

The bulk of Plaintiffs' argument regarding the reliability of Dr. Drolet's risk/benefit opinion focuses on Dr. Drolet's testimony from *Gomez* that she was "unaware of any clinical benefits associated with Prolift+M as compared to Prolift." Pls.' Br. [Dkt. 2094] at 4 (emphasis added). Plaintiffs' argument is premised on a nonsequitor: that Dr. Drolet must espouse a clinical

benefit of Prolift+M as compared to Prolift in order to find that Prolift+M's benefits outweighed its risks. The Prolift+M and Prolift may have identical benefit-profiles and simultaneously the benefits of Prolift+M can still outweigh its risks. Plaintiffs' objection along this line is premised on nothing more than a logical fallacy.

III. Dr. Drolet Is Well Qualified To Opine Regarding the General State of Medical Knowledge

Plaintiffs argue that Dr. Drolet should not be allowed to opine that complications associated with Prolift+M and TVT-O were "well known." Pls.' Br. [Dkt. 2094] at 5. Dr. Drolet is a board certified pelvic reconstruction surgeon with more than 20 years of clinical experience. Ex. A, Drolet CV at 1. She is, without question, a bona fide expert in the field of pelvic floor surgery. *See generally id.*

Plaintiffs' argument that Dr. Drolet should be prohibited from opining on the state of medical knowledge stems first from Plaintiffs' misstatement of Dr. Drolet's opinion testimony. Plaintiffs allege that Dr. Drolet seeks to opine what risks are known by "'all' physicians." Pls.' Br. [Dkt. 2094] at 5 (emphasis added). Nowhere in her reports does Dr. Drolet attempt to say what "is" known by "all" physicians. She never attempts to impute knowledge to any individual surgeon or any class of surgeons.

Rather, Dr. Drolet provides descriptions of the risks associated with both non-mesh and mesh surgeries. She supports those descriptions with published medical literature. Dr. Drolet opines that the risks that are not unique to mesh surgeries are well known within the general state of knowledge in the medical community. Further, Dr. Drolet opines that the reasonably prudent pelvic floor surgeon would apprise herself of this general medical knowledge. For example, Plaintiffs complain about Dr. Drolet's statement that "[a] reasonably prudent pelvic floor surgeon performing incontinence and prolapse surgeries would have already been aware of the potential

for these complications." *See* Pls.' Br. [Dkt. 2094] at 5 (quoting Drolet *Gomez* Report at 18). This is an opinion regarding the risks associated with non-mesh surgeries and the fact such risks were commonly known before Prolift, Prolift+M, or TVT-O were first marketed.

Dr. Drolet's opinion testimony regarding what was known by the medical community is directly relevant to Ethicon's learned intermediary defense to Plaintiffs' failure to warn claim and consistent with the governing legal standard and should therefore be admitted in its entirety. The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D.W. Va. 2009) (adopting "sophisticated user" defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of person whose use is at issue in the particular case. *Johnson v. American Standard, Inc.*, 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

So the important question with respect to Plaintiffs' failure to warn claim is what "hazards" were "commonly known" to surgeons familiar with traditional non-mesh prolapse and SUI surgeries and mesh surgery before Prolift, Prolift+M, or TVT-O were introduced. Dr. Drolet is qualified by her experience and her examination of the literature to identify the risks that are commonly known.

IV. Dr. Drolet Does Not Seek to Opine Regarding the Intent of the Medical Device Industry, Ethicon, or the FDA

Plaintiffs point to only four instances of Dr. Drolet allegedly attempting to opine on the intent of the industry, Ethicon, or the FDA:

- "The introduction of mesh in the treatment of [POP] was intended to attain an important goal of surgeons – improve the longevity of the repair." Pls.' Br. [Dkt. 2094] at 6.
- "The Prolift+M was eventually developed by Ethicon in order to continue innovation, continue to maintain efficacy and durability." *Id.* at 7.
- "Overall the design of the Posterior Prolift and Prolift+M not only made sense but it was consistent with the decades-long march towards optimizing correction of prolapse." *Id.*
- "Pelvic floor surgeons were the target audience of this [FDA] notification and would have been expected to read and consider the notice." *Id.*

Ethicon addresses each in turn.

Plaintiffs' first challenged statement is presented out of context. Dr. Drolet describes the historical underpinnings of using mesh in pelvic floor repairs. *See* Ex. B, Drolet Prolift Report [Dkt. 2093-2] at 14. Surgeons—not the medical device industry—initiated the use of synthetic mesh in pelvic floor reconstruction. *Id.* The published and stated reason for surgeons making this move toward pelvic mesh was to increase the durability of the repair. Dr. Drolet is describing the published medical literature, which captures the medical judgment of the pioneers of synthetic mesh pelvic floor repair surgeries. She is not attempting to opine on the intent or state of mind of the medical device industry.

The second challenged statement—regarding the development of Prolift+M—does not attempt to opine on the intent of Ethicon. Prolift+M development was part of a linear progression of mesh repair options. Dr. Drolet merely acknowledges that Prolift+M was the next step in that linear progression.

Similarly, the third challenged statement—that Prolift+M made sense and was consistent with the decades-long march towards optimization—is merely recognition of Prolift+M's place within the linear progression of POP repair devices. Nothing about this statement goes to the intent of Ethicon.

The last statement challenged by Plaintiffs concern the FDA Public Health Advisory. Dr. Drolet says that this advisory was aimed at physicians. This is clear and evident on the face of the advisory. Dr. Drolet need not attempt to get into the mind of FDA to reach the opinion that the advisory was aimed at physicians. The Public Health Advisories are documents published by the FDA, for use by physicians, and form part of the general knowledge of the medical community.

V. Dr. Drolet Does Not Intend to Opine on the Significance of Obtaining FDA 510(k) Clearance

The only references to the FDA 510(k) clearance appear on Page 15 of Dr. Drolet's Prolift Report and Page 16 of her TVT-O Report. Her statements are made in reference to the timeline of events leading to the marketing of the products. Nowhere in her Reports does Dr. Drolet offer an opinion regarding the significance of FDA 510(k) clearance relative to a determination of safety and efficacy.[2]

In her deposition, however, Plaintiffs asked Dr. Drolet, "If you had seen internal Ethicon documents describing Ethicon's choices not to perform animal testing prior to marketing the device, would that have been helpful in formulating your opinion about whether or not this was a safe and effective device?" Drolet (3/31/16) Dep. Tr. [Dkt. 2093-3] at 87:14-87:20. Dr. Drolet's answered "[i]t depends." *Id.* at 87:22. Plaintiffs asked Dr. Drolet upon what did it depend, and Dr. Drolet answered "if the FDA cleared [Prolift+M], then it was going to be safe." *Id.* at 87:24-

[2] Ethicon is aware of the Court's prior rulings regarding the admissibility of evidence of FDA regulatory compliance and does not attempt to reargue its position here.

88:7. Plaintiffs then went into follow-up questions regarding the 510(k) clearance process and its relationship to a determination by the agency of safety and efficacy. *See id.* at 88:8-89:9. Dr. Drolet answered Plaintiffs' questions. *Id.*

Dr. Drolet does not intend to offer her opinions about the FDA 510(k) clearance process. But she should be permitted to answer fully any questions posed by Plaintiffs. Dr. Drolet cannot be faulted for honestly answering Plaintiffs' questions. Plaintiffs' objection to 510(k) opinions should be resolved by Plaintiffs avoiding questions that elicit such response from Dr. Drolet.

VI. Dr. Drolet's Opinions that the IFU Contained the Appropriate Risks Are Reliable and Admissible

Plaintiffs argue that Dr. Drolet cannot offer opinions about the IFU because she is "not qualified to act as a regulatory expert" and because her "opinions regarding the adequacy of the IFU are simply made up." Pls.' Br. [Dkt. 2094] at 8.

As an initial matter, whether the IFUs advised physicians of the risks associated with the products is not a regulatory opinion. True, there are federal regulations in place that govern the contents and form of an IFU, but Dr. Drolet is not opining as to whether the IFUs satisfied the regulatory requirements.

Similarly, Plaintiffs attack Dr. Drolet because she "never reviewed Ethicon's internal procedures or documents concerning the contents of an IFU." *Id.* at 8. Again, Dr. Drolet is not opining as to whether the IFUs met Ethicon's internal policies.

Dr. Drolet's opinion is that "the applicable Prolift IFU at the time, as well as the Prolift+M IFU which incorporated and was supplemented by professional education and the surgical technique guide, warned pelvic surgeons of the appropriate risks and complications related to the Prolift & Prolift+M." Ex. B, Drolet Prolift Report at 31; *see also* Ex. C, Drolet TVT-O Report at 25 ("[T]he applicable TVT-O IFUs appropriately warned pelvic surgeons of

the potential risks and complications specific to the TVT-O."). Dr. Drolet's opinion in this regard is well grounded in both her clinical experience using Prolift, Prolift+M, TVT-O, and other medical devices and her review of the relevant medical literature. Plaintiffs' argument—that Dr. Drolet's opinions are inadmissible because she did not rely on FDA regulations or internal Ethicon protocols—rests entirely on the supposition that expertise in FDA regulations related to requirements for IFUs is mandatory for these opinions.

Yet, the job of an expert witness is to provide the facts to which the court can apply the law. It is not the expert's job to provide the court with the law. This Court, in fact, has excluded testimony which not only stated facts but also expressed a legal conclusion. *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation (Lewis)*, 2014 WL 186872 (S.D. W. Va. 2014) at *20 (citing *United States v. McIver,* 470 F.3d 550, 562 (4th Cir. 2006)). The important question here is whether Dr. Drolet's testimony is consistent with the law to be applied to the case, and not whether she herself could articulate the governing legal standard. If she had attempted to do that, her testimony would have been excluded.

Dr. Drolet's IFU opinions and qualifications to offer those IFU opinions are similar to those previously found to be admissible by this Court. In *Trevino v. Boston Scientific Corp.*, 2:13-CV-01617, 2016 WL 2939521, at *13-14 (S.D.W. Va. May 19, 2016), the defendant sought to exclude the warnings testimony of plaintiff's urogynecologist Bobby L. Shull, M.D. There, the defendant argued that Dr. Shull was not qualified to opine on the adequacy of the IFU because Dr. Shull "is not an expert in the regulations or standards that govern [IFUs]; he has never advised a company on a[n IFU]; he is unfamiliar with the industry process governing [IFUs]; and he has not even performed a literature search relating to DFUs." *Id.* at * 13. The plaintiff noted that Dr. Shull had not been designated to offer any opinions regarding the manner by which the

defendant developed the IFU or the regulatory requirements applicable to IFUs. *Id.* Instead, Dr. Shull was only offered "to opine on the completeness and accuracy of the [product's] warnings from a clinical perspective." *Id.* at *40-41. This Court held that Dr. Shull's testimony along these lines would be admissible:

> Dr. Shull will testify about the risks he perceives that the Uphold poses to patients, and he will opine that that the Uphold DFU did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison. *See, e.g., Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014) (finding Dr. Blaivas, a urologist, qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's DFU); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs] ... and to compare that knowledge with what was provided in the text of labeling and warnings ...." (quoting *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, at 11 (E.D. Pa. June 20,2000))). I also find that Dr. Shull's forty years of experience, along with his evaluation of medical literature forms a reliable basis for this testimony. *Kumho Tire Co.*, 526 U.S at 156 (stating that "an expert might draw a conclusion from a set of observations based on extensive and specialized experience").

Id. Just like Dr. Shull, Dr. Drolet is relying on her years of clinical experience and her review of the medical literature to identify the risks associated with Prolift, Prolift+M, and TVT-O and opines that the respective IFUs did warn physicians of the risks.

As discussed above, the legal principle that controls here is that a device manufacturer's duty to warn of adverse events is limited to events unique to the device. It does not include a duty to warn of risks commonly known to the surgeons who use the device. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j (seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users."); *see also* RESTATEMENT (SECOND) OF THE LAW

OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D.W. Va. 2009) (adopting "sophisticated user" defense in §388).

This limitation on the duty to warn is recognized in medical device cases as well. There is no duty to warn of risks that implanting surgeons commonly know. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community"). In fact, the FDA regulations recognize that that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c) (emphasis added).

Here, the devices' IFUs restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. *See* Ex. D, Prolift IFU (ETH.MESH.02341459) at 6 ("Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLICT Pelvic Floor Repair Systems."); Ex. E, Prolift+M IFU (ETH.MESH.01595615) at 2 ("Physicians should have experience in management of complications resulting from procedures using surgical mesh. . . . Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing the GYNECARE PROLIFT+M™ Systems."); Ex. F, TVT-O IFU at 1 (ETH.MESH.00860240) ("This package insert is designed to provide instruction for use of the GYNECARE TVT* Obturator System . . . . It is not a comprehensive reference to surgical technique for correcting SUIT (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in

implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device.").

Again, the important question with respect to Plaintiffs' failure to warn claim is: what "hazards" and are "commonly known" to surgeons familiar with pelvic surgery, including surgery to address pelvic organ prolapse and SUI? That is precisely the opinion reached by Dr. Drolet. She reviewed the risks associated with non-mesh surgical repair. *See* Ex. B, Drolet Prolift Report at 7-10. Dr. Drolet then examined the risks associated with mesh surgical repair. *See id.* at 18-22. And she ultimately concludes that the risks "specific to the device, primarily, mesh erosion and scarring that can results in implant contraction, have been included in the IFU since Prolift was first launched." *Id.* at 24-25. Dr. Drolet is competent to offer this opinion; she arrives at her opinion through a reliable methodology.

Ethicon is mindful of the Court's Wave 1 rulings that experts without additional regulatory expertise on product labeling and compliance cannot testify "about what an IFU should or should not include." *See, e.g., In re: Ethicon, Inc.*, 2016 WL 4557036, at *3. But that is not what Dr. Drolet is doing here. She will not offer opinions about what should or should not be included in an IFU. Rather, through her own experience and her examination of the medical literature, she (1) identifies the risks associated with non-mesh pelvic floor surgery and SUI surgery, (2) identifies the risks associated with mesh pelvic floor surgery ad SUI surgery, (3) compares the non-mesh risks to the mesh risks to determine which, if any, are unique to the mesh surgeries, and (4) offers her opinion as to whether the IFUs warned physicians of the risks unique to the mesh surgeries.

Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings.

It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Drolet's conclusion can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 532.

VII. Dr. Drolet Does Not Offer Any Legal Conclusions

Plaintiffs point to only one alleged "legal conclusion" offered by Dr. Drolet—that the IFUs "adequately warned pelvic surgeons." Pls.' Br. [Dkt. 2094] at 9 (citing Drolet *Gomez* Report at 27). This alleged legal conclusion does not appear in either of the reports at issue in Wave 4. *See generally* Ex. B, Drolet Prolift Report; Ex. C, Drolet TVT-O Report. Accordingly, Plaintiffs' argument is moot.

Moreover, this is not a legal conclusion, this is a factual opinion. While this opinion does "embrace an ultimate issue" that the jury must decide, it is not objectionable just because it does so. *See* Fed. R. Evid. 704.

As this Court recently noted, experts should not be allowed to "state[] a legal standard," "draw[] a legal conclusion by applying the law to the facts" of the case, or "using 'legal terms of art,' such as 'defective,' 'unreasonably dangerous,' or 'proximate cause.'" *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at *3 (S.D.W. Va. May 19, 2016). Dr. Drolet attempts none of these things. Rather, she opines that, as a physician experienced in the implantation of pelvic floor devices, Ethicon sufficiently apprised her and other reasonably prudent physicians of the risks associated with the products. Whether these warnings were sufficient to render the products non-defective or not unreasonably dangerous (i.e., the ultimate legal conclusions) remain questions within the sole province of the jury.

VIII. Dr. Drolet Sufficiently Identified the Materials Upon Which She Relied

In conjunction with her *Gomez* report, Dr. Drolet supplied a list of all documents made available to her and upon which she relied when arriving at her opinions. During her deposition in *Gomez*, Plaintiffs questioned Dr. Drolet regarding whether she read certain documents contained on that listing and, if so, what role those documents played in her opinion. Dr. Drolet testified that she did not recall reading certain of the documents contained on the list. Plaintiffs contend—without any citation to a legal authority—that somehow this renders her testimony inadmissible.

First, it should be noted that Plaintiffs have not deposed Dr. Drolet in relation to the two reports at issue in Wave 4. The report and testimony cited by Plaintiffs refer only to *Gomez*.

Regardless, Dr. Drolet sufficiently identified the documents upon which she relied in her Wave 4 reports. In fact, her reports are replete with citations to the articles, studies, RCTs, meta-analysis, position papers, and other documents upon which she relied. That Dr. Drolet had in her possession more documents than those cited in her expert report is not a basis for excluding her testimony.

Again, if Plaintiffs believe there is information in these other documents—both those Dr. Drolet possessed and those she did not possess—that contradict her opinions, Plaintiffs can attempt to cross-examine her with those documents. But not reading or not recalling having read a document does not render Dr. Drolet's opinion testimony unreliable.

Similarly, Plaintiffs complain that Dr. Drolet was not provided with certain depositions of current and former Ethicon employees. Again, this is a point for cross-examination, not *Daubert*.

Lastly, Plaintiffs contend that Dr. Drolet testified that "these materials might alter her expert opinions about the Prolift device." Pls.' Br. [Dkt. 2094] at 11. Nowhere do Plaintiffs cite

anything to support this assertion. Dr. Drolet has not testified that the contents of the Ethicon employee depositions "might alter her expert opinions." That assertion is pure speculation on Plaintiffs' part.

CONCLUSION

For the above reasons, Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson respectfully request that this Court enter an order denying Plaintiffs' Motion to Exclude Certain Testimony of Julie Drolet, M.D. [Dkt. 2093].

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/Christy D. Jones

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